Docket No.: 341148020US

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wright et al.

Application No.: 10/750,164 | Confirmation No.: 5009

Filed: December 31, 2003 | Art Unit: 3737

For: MARKER LOCALIZATION SENSING SYSTEM SYNCHRONIZED WITH RADIATION SOURCE | Examiner: J. M. Kish

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As required under § 41.37(a), this brief is filed one month from the mailing of the Notice of Panel Decision from the Pre-Appeal Brief Review, and is in furtherance of the Notice of Appeal.

Any fees required under § 41.20(b)(2) are remitted in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I. Real Party In Interest
II Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Calypso Medical Technologies, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 15 claims pending in the application.

B. Current Status of Claims

1. Claims canceled: none
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 1-15
4. Claims allowed: none
5. Claims rejected: 1-15

C. Claims On Appeal

The claims on appeal are claims 1-15

IV. STATUS OF AMENDMENTS

Applicant did not file an Amendment After Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Each independent claim being appealed is paraphrased below, with citations to the corresponding portions of the specification and drawings as required by 37 C.F.R. §41.37(c)(1)(v). These citations are provided in order to illustrate specific examples and embodiments of the recited claim language and are not intended to limit the claims.

A. Claim 1

Independent claim 1 is directed to a receiver for use in receiving a plurality of inputs indicative of a sensed magnetic flux induced by a marker, wherein the marker is excited by an excitation source. The receiver includes, *inter alia*, a sensor configured to receive a plurality of inputs. (*See, e.g.,* specification at pg. 12, *The Receiver*, ¶ 3; pg. 14, ¶ 1 starting with "The above"; and Figure 5, reference character 208). The receiver also includes a correlation processor for analyzing the plurality of inputs in a coherent manner and for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs. (*See, e.g.,* specification at pg. 18, ¶ 5 through pg. 19, ¶ 1; and pg. 19, ¶ 4 starting with the word "Therefore"). The inputs that are acquired when a therapeutic radiation source is active are considered corrupted. (*See, e.g.,* specification at pg. 18, ¶ 5 through pg. 19, ¶ 1; and pg. 19, ¶ 4 starting with the word "Therefore").

B. Claim 6

Independent claim 6 is directed to a method of irradiating a patient with radiation from a therapeutic radiation source, wherein the radiation is targeted by the use of a marker associated into the patient. The method includes, *inter alia*, applying an excitation to the marker using an excitation source. (*See, e.g.,* specification at pg. 4, ¶ 2; and Figure 7, reference block 701). The method further includes using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to the

excitation. (*See, e.g.,* specification at pg. 12, *The Receiver*, ¶ 3; pg. 14, ¶ 1 starting with "The above"; and Figure 5, reference character 208). The method further includes discarding selected data from the plurality of inputs to generate a subset of the plurality of inputs such that the subset of the plurality of inputs includes data gathered when the receiver was not subject to interference from the therapeutic radiation source. (*See, e.g.,* specification at pg. 18, ¶ 5 through pg. 19, ¶ 1; and pg. 19, ¶ 4 starting with the word "Therefore"). The method also includes using a processor to perform an analysis on the subset of the plurality of inputs in a coherent manner to locate the marker. (*See, e.g.,* specification at pg. 14, ¶ 6 through end of paragraph on pg. 15; and Figure 5, reference character 504).

C. Claim 11

Independent claim 11 is directed to a method of irradiating a patient with radiation from a therapeutic radiation source, the radiation targeted by the use of a marker associated into the patient. The method includes, *inter alia*, applying an excitation to the marker using an excitation source. (*See, e.g.,* specification at pg. 4, ¶ 2; and Figure 7, reference block 701). The method further includes using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to the excitation. (*See, e.g.,* specification at pg. 12, *The Receiver*, ¶ 3; pg. 14, ¶ 1 starting with "The above"; and Figure 5, reference character 208). The method also includes discarding corrupted inputs subject to interference from the therapeutic radiation source from the plurality of inputs to create a subset of the plurality of inputs. (*See, e.g.,* specification at pg. 18, ¶ 5 through pg. 19, ¶ 1; and pg. 19, ¶ 4 starting with the word "Therefore"). The method further includes using a processor to perform an analysis on the subset to locate the marker. (*See, e.g.,* specification at pg. 14, ¶ 6 through end of paragraph on pg. 15; and Figure 5, reference character 504).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 6 and 11 are unpatentable over claims 1 and 6 of U.S. Patent No. 7,026,927 ("the '927 patent") under the doctrine of obviousness-type double patenting.

B. Whether claims 1, 2, 4-7, 9-12, 14 and 15 are unpatentable over U.S. Patent Application No. 2002/0193685 to Mate et al. ("Mate") under 35 U.S.C. § 103(a).

C. Whether claims 3, 8 and 13 are unpatentable over Mate in view of U.S. Patent No. 5, 729,129 to Acker et al. ("Acker") under 35 U.S.C. § 103(a).

VII. ARGUMENT

A. Rejections Under the Doctrine of Obviousness-Type Double Patenting

Claims 1, 6 and 11 were rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of the '927 patent. The '927 patent and the current application are commonly owned. Applicants submitted a Terminal Disclaimer in accordance with C.F.R. § 1.321 on June 5, 2007. Because this rejection was first raised in the Final Office Action, the applicants submit that the Terminal Disclaimer was filed in a timely manner. Therefore, applicants submit that the double patenting rejection is moot.

B. Rejections Under 35 U.S.C. § 103(a) are improper

1. Legal Standards for Obviousness

Claims 114-144 and 154-158 on appeal stand rejected as obvious under 35 U.S.C. § 103(a). 35 U.S.C. § 103(a) provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references

> themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

M.P.E.P § 2142.

To properly reject claims as obvious, "the examiner bears the initial burden of presenting a *prima facie* case of obviousness." *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d (BNA) 1955, 1956 (Fed. Cir. 1993). The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459 (1966), stated:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

To establish a *prima facie* case of obviousness, the Examiner must (1) identify prior art references that disclose all the elements of the claims, and (2) provide a suggestion or motivation to modify the references to produce the claimed invention. M.P.E.P. § 2143. With respect to the second requirement, the Examiner must provide a suggestion or motivation to combine from within the prior art, and may not rely upon hindsight gleaned from applicants' invention itself. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.,* 837 F.2d 1044, 1050-51, 5 U.S.P.Q.2d (BNA) 1434, 1438 (Fed. Cir. 1988).

The recent Supreme Court decision in *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350, slip op. at 14 (U.S. Apr. 30, 2007) reaffirmed the holdings of *Graham*, and clarified several aspects of the manner in which obviousness should be determined. *KSR*, p. 11. First, "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results," but "when the prior art teaches away from combining certain elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, p. 12. Second, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art," rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, p. 14-15. The Court recognizes that many significant advances will combine familiar elements: "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR*, p. 15.

Following the decision in *KSR*, the USPTO issued a memorandum to all Examiners. The memorandum directs Examiners to continue to determine why a person of ordinary skill in the art would make the combination, "in formulating a rejection under 35 U.S.C. 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." "Supreme Court decision on *KSR Int'l v. Teleflex, Inc.*," May 3, 2007, p. 2.

A motivation or suggestion to combine should come from the prior art. *In re Zurko,* 258 F.3d 1379, 1385-86, 59 U.S.P.Q.2d (BNA) 1693, 1697 (Fed. Cir. 2001); *In re Rijckaert*, 9 F.3d at 1532, 28 U.S.P.Q.2d (BNA) at 1956. The Examiner has not pointed to any teaching or suggestion within the prior art that supports his conclusory statements about a motivation or suggestion to combine. Rather, the Examiner's statements are a classic—and legally impermissible—use of hindsight. The Examiner recognizes some of the improvements contributed by applicants' invention, and attempts to attribute those improvements to some sort of common sense or background knowledge available to anyone of ordinary skill in the art at the time of the invention. The Federal Circuit has consistently held that reliance on such common sense or basic knowledge is impermissible. *Id.*; *see also In re Sang Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d (BNA) 1430 (Fed. Cir. 2002). No teaching or motivation from within the prior art suggested combining the cited art, and the Examiner's conclusory statements are insufficient. The pending claims should be allowed.

Furthermore, if the Examiner suggests that an element of the claim is inherent in the prior art, the Examiner must provide rationale or evidence tending to show inherency. M.P.E.P. § 2112. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. M.P.E.P. § 2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981)). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." M.P.E.P. § 2112 (citing *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.)). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." M.P.E.P. § 2112 (citing *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 U.S.P.Q.2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

"In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

M.P.E.P. § 2112 (citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients. The Examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular perform and then injecting air into the perform to expand it against a mold (blow molding). The reference did not directly state that the end production balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The Examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the Examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.)). M.P.E.P. § 2112 goes on to state "[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations." M.P.E.P. § 2112 (citing *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *see also Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1367 (Fed. Cir. 1991)).

Under these legal standards, the applicants' invention would not have been obvious. The Examiner does not identify prior art references, or a combination thereof, that disclose all the elements of the pending claims. Moreover, the Examiner has failed to identify a sufficient reason why a person of ordinary skill in the art would find the claimed invention obvious over Mate, or Mate in combination with Acker. Therefore, the claims on appeal should be allowed.

2. Summary of the Claimed Subject Matter

The claims recite a receiver and methods for use in receiving a plurality of inputs indicative of a sensed magnetic flux induced by a marker, wherein the marker is excited by an excitation source. As explained in more detail below, claim 1 recites a correlation

processor for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs; claims 6 recites a correlation processor for discarding selected data from the plurality of inputs to generate a subset of the plurality of inputs; and claim 11 recites a correlation processor discarding corrupted inputs subject to interference from the therapeutic radiation source from the plurality of inputs to create a subset of the plurality of inputs.

With reference to the Figure 5 shown below, sense coils 302 each provide a signal to a respective amplifier 404. The amplifier 404 then provides the amplified signal to an associated analog to digital (A/D) converter 502 that converts the analog amplified signal into a digital representation. The receiver 208 will act on the plurality of digital inputs to substantially eliminate noise, interference and other "non-signal" effects to provide a plurality of high signal-to-noise ratio (SNR) digital outputs. The receiver may further include a matched filter or other device (designated as radiation detector 512 in Figure 5) that can detect the presence of interference due to the operations of the radiation delivery apparatus or any other interfering device that operates in a pulsed mode. If such interference is detected, then the receiver 208 is operative to discard received input signals from the coils 302 that occurred in that time frame.

The receiver 208 further includes a correlation processor 504, which may analyze the plurality of inputs in a coherent manner and may generate a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs. Corrupted inputs are acquired when a therapeutic radiation source (shown as incoming arrow) is detected as active by radiation detector 512.

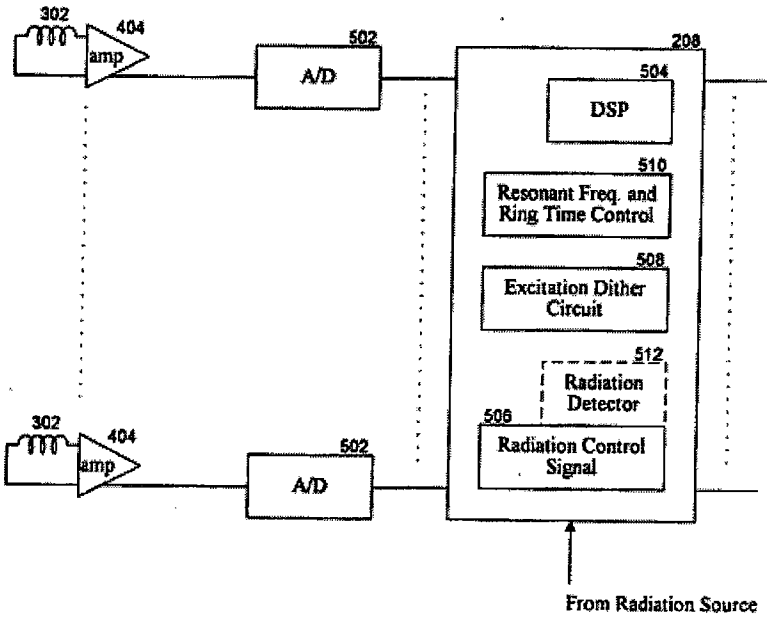

FIG. 5

3. The Examiner has not established a *prima facie* case of obviousness of claim 1 because Mate fails to disclose each and every element

To establish a *prima facie* case of obviousness, three criteria must be met. (MPEP § 2142.) "First, there must be some suggestion or motivation...to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP §§ 2143 and 2143.03.) In the present case, the applied reference does not teach or suggest a correlation processor for 1) generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs, and 2) discarding selected data from the plurality of inputs to generate a subset of the plurality of inputs such that the subset of the plurality of inputs includes data gathered when the receiver was not subject to interference from the therapeutic radiation source.

i. <u>Mate Discloses a Target Locating and Tracking System, Having One or More Excitable Markers, an External Excitation Source,</u>

a Plurality of Sensors, and a Computer Coupled to the Sensors and Configured to Identify a Target Isocenter.

According to the abstract of Mate, and with reference to Figure 6 shown below, Mate is directed:

> A system and method for accurately locating and tracking the position of a target [40], such as a tumor or the like, within a body. In one embodiment, the system is a target [40] locating and monitoring system usable with a radiation delivery source that delivers selected doses of radiation to a target in a body. The system includes one or more excitable markers [30] positionable in or near the target [40], an external excitation source [32] that remotely excites the markers [30] to produce an identifiable signal, and a plurality of sensors [36] spaced apart in a known geometry relative to each other. A computer [38] is coupled to the sensors [36] and configured to use the marker measurements to identify a target isocenter within the target [40]. The computer [38] compares the position of the target isocenter with the location of the machine isocenter [22]. The computer [38] also controls movement of the patient and a patient support device so the target isocenter is co-incident with the machine isocenter [40] before and during radiation therapy.

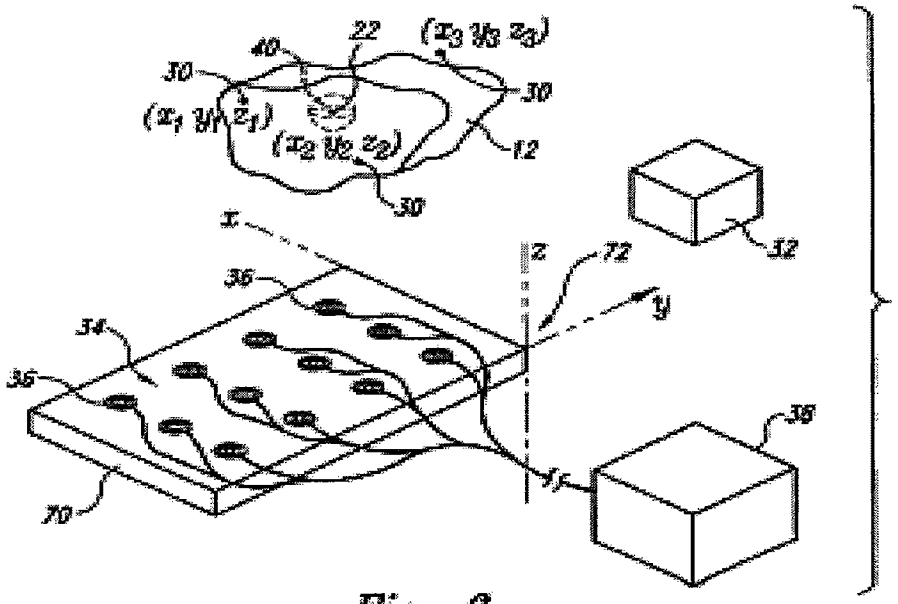

Fig. 6

Additionally, Mate teaches that "the marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways." (Mate; ¶ 0053).

ii. Mate Fails to Support a Prima Facie Case for Rejecting Claim 1 Under Section 103 for at Least the Reason that His Reference Fails to Disclose or Suggest Generating a Subset of the Plurality of Inputs.

Mate fails to support a *prima facie* case for rejecting claim 1 under Section 103 for at least the reason that his reference fails to disclose or suggest generating a subset of the plurality of inputs. Independent claim 1 discloses (**a**) generating a subset of the plurality of inputs by (**b**) discarding corrupted inputs from the plurality of inputs, wherein (**c**) inputs that are acquired when a therapeutic radiation source is active are considered corrupted. In contrast, Mate discloses a computer controller that calculates the location of the machine isocenter relative to the sensor array. (Mate; ¶ 0038). Moreover, the "signal line" between the controller computer 38 and radiation delivery source at item 42 (referred to in the Office Action at page 3) is useful for detecting positional information relevant to the radiation isocenter. (Mate; ¶ 0038). The "signal line" is not disclosed as communicating information relevant to activity (i.e. therapeutic source activity state). Indeed, Mate is silent with respect to the therapeutic radiation source signal and therefore, does not disclose or suggest creating a subset of data by discarding corrupted inputs, wherein the input is considered corrupted when the therapeutic radiation source is active.

In the Final Office Action, the Examiner erroneously states that Paragraph 53 "describes a method for removing data that has been corrupted by an excitation source." The Examiner is incorrect. Paragraph 53 of Mate states that the "marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways" in order to allow the receiver to differentiate between the marker signal and the excitation source. (Mate, ¶0053). The marker's

excitation signal and response signal are being differentiated; corrupted data is not being removed as stated by the Examiner. The Examiner then erroneously concludes that "broadly interpreted, this is describing filtering of relevant data from noise from an outside source." (Office Action; pg. 3). Again, the Examiner is incorrect. The marker's excitation signal is being differentiated from the marker's response signal (both of which are within the control of Mate) in order to locate the marker. Mate does not teach, suggest, or disclose a method for discarding input which has been corrupted by an incoming radiation signal. Thus, the Examiner is incorrect in his rejection of claim 11, and the Board should reverse this rejection.

Furthermore, Mate discloses methods of differentiating a signal generated by the excitation source from the marker's response signal. For example, the excitation source turned or gated "on" to excite the marker then turned or gated "off" to allow for measurement of the marker response without interference by the signal from the excitation source. (Mate; ¶ 0053). Other methods include having the excitation source remain "on" during measurement of the markers and have the marker signal 90 degrees "out of phase" with the signal from the excitation source, so the marker signal is removed from the excitation signal for each data input. (Mate; ¶ 0053). As discussed and agreed upon during the telephonic Examiner's interview on June 9, 2006, the excitation source of Mate and the claimed invention is not equivalent, interchangeable, nor rendered obvious by the therapeutic radiation source of concern in the claimed invention. In a specific example, the computer controller of Mate has control of the "on" and "off" status as well as the phase of the excitation signal from the excitation source, thus allowing Mate to differentiate between the signal generated by the marker's excitation source and the marker's response signal. These elements contribute to the calculations necessary to filter relevant data from noise from the excitation signal. The claimed invention is directed toward the removal of data inputs in their entireties that are generated when a therapeutic radiation source is active. The claimed features include generating a subset of input by removing input corrupted by

an outside source, namely, the therapeutic radiation source, for which the present invention accounts for, but which is not controlled in the system.

Based on the foregoing, it is clear that Mate does not teach or suggest (**a**) generating a subset of the plurality of inputs by (**b**) discarding corrupted inputs from the plurality of inputs, wherein (**c**) inputs that are acquired when a therapeutic radiation source is active are considered corrupted. Therefore, the Examiner has not established a *prima facie* case of obviousness with respect to claim 1, and the Board should reverse the Examiner's rejection of claim 1 for at least this reason.

4. The receiver of claim 1 is nonobvious to a person of ordinary skill in the pertinent art under the statutory language of § 103(a), as analyzed according to the framework set forth by the Supreme Court

As noted previously, in the recent Supreme Court case of *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), the Supreme Court reaffirmed the framework set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), for applying the statutory language of § 103(a). The *Graham* framework requires that the Examiner perform the following analysis:

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined.

(*KSR*, slip op. at 2 (quoting *Graham* at 17-18).)

Furthermore, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal standard of obviousness." *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The Examiner has not analyzed claim 1 (or any of the other pending claims, for that matter) in accordance with the *Graham* framework, for at least the reason that the Examiner has not resolved the level of ordinary skill in the

pertinent art, as required by *Graham* and *KSR* and as noted in MPEP § 2141. ("Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case.").

The Examiner erroneously asserts that "[r]egardless of whether the source is the actual excitation source or a therapeutic source, it would be obvious to one of skill in the art to remove erroneous data from a localization signal in order to localize the target correctly." Office Action, December 5, 2006 at page 3. Such reasoning is simply a conclusion and does not satisfy the established guidelines or recent directives. Contrary to the Examiner's assertion, there are numerous and significant differences between the pending claims and the applied references. The claimed invention is drawn to removal of data input in its entirety if the input was generated while a therapeutic radiation source is active. Mate discloses differentiating between an excitation signal and a response signal. The Examiner's merely conclusory statement fails to provide a reasoned statement for why one skilled in the art would generate a subset of the plurality of inputs by discarding corrupt inputs, wherein the inputs that are acquired when the therapeutic radiation source is active are considered corrupted.

These differences are not such that the subject matter of claim 1 as a whole would have been obvious to a person of ordinary skill in the pertinent art. This is true for at least the reason that such a person would not have found it obvious to consider the teachings of Mate to arrive at a receiver that receives a plurality of inputs that includes (**a**) generating a subset of the plurality of inputs by (**b**) discarding corrupted inputs from the plurality of inputs, wherein (**c**) inputs that are acquired when a therapeutic radiation source is active are considered corrupted. The Examiner asserts that it would have been an obvious matter of design choice "to remove erroneous data from a localization signal in order to localize the target correctly." Applicants disagree. The Examiner has failed to articulate a reasoned statement for why someone skilled in the art would know that data was corrupted or how, once identified, it would be removed. Further, the Examiner has failed to supply a

reference or reasoned statement for designating input "acquired when a therapeutic radiation source is active" as corrupted as claimed. Applicants respectfully submit that the only motivation for generating a subset by discarding corrupt data is found in the claimed invention, and thus, the Examiner has not satisfied the obviousness standard, even under *KSR*. For this additional reason the Board should reverse the Examiner's rejection of claim 1.

5. Claims 2 and 4-5

Claims 2 and 4-5 depend from base claim 1. Accordingly, Mate cannot support a § 103(a) rejection of dependent claims 2 and 4-5 for at least the reason that these references cannot support a § 103(a) rejection of base claim 1, and for the additional reasons that Mate does not teach or disclose the receiver claimed in claim 1 for use in the treatment of a human; does not teach or disclose a signal line between the therapeutic radiation source and the receiver which carries a signal indicative of activity of the therapeutic radiation source; and does not teach or disclose the receiver claimed in claim 1 wherein the radiation source is a linear accelerator. Therefore the Board should reverse the Examiner's rejection of claims 2 and 4-5.

6. Claim 6

Independent claim 6 is directed to a method of irradiating a patient with radiation from a therapeutic radiation source, wherein the radiation is targeted by the use of a marker associated into the patient. The method includes, *inter alia*, applying an excitation to the marker using an excitation source. The method further includes using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to the excitation. The method further includes discarding selected data from the plurality of inputs to generate a subset of the plurality of inputs such that the subset of the plurality of inputs includes data gathered when the receiver was not subject to interference from the therapeutic radiation source. The method also includes using a processor to

perform an analysis on the subset of the plurality of inputs in a coherent manner to locate the marker.

a. The Examiner has not established a *prima facie* case of obviousness of claim 6

As previously noted, to establish a *prima facie* case of obviousness, the Examiner must identify references that teach or suggest all the features of the claim. As discussed with respect to claim 1 above, Mate does not teach or suggest (**a**) discarding selected data from the plurality of inputs to (**b**) generate a subset of the plurality of inputs such that the subset of the plurality of inputs includes (**c**) data gathered when the receiver was not subject to interference from the therapeutic radiation source. Because this reference is deficient in this regard, the Examiner has not established a *prima facie* case of obviousness of claim 6. For at least this reason the Board should reverse the Examiner's rejection of claim 6.

b. The method of claim 6 is nonobvious to a person of ordinary skill in the pertinent art under the statutory language of § 103(a), as analyzed according to the framework set forth by the Supreme Court

As previously noted, one difference between the subject matter of claim 6 and Mate is that claim 6 recites (**a**) discarding selected data from the plurality of inputs to (**b**) generate a subset of the plurality of inputs such that the subset of the plurality of inputs includes (**c**) data gathered when the receiver was not subject to interference from the therapeutic radiation source. This is a feature that is neither taught nor suggested by the applied reference. Mate discloses methods of separating signals generated by the excitation source from signals generated by the marker source.

These differences are not such that the subject matter of claim 6 as a whole would have been obvious to a person of ordinary skill in the pertinent art. The Examiner asserts that it would have been an obvious matter of design choice to "to remove erroneous data from a localization signal in order to localize the target correctly." As previously stated, the applicants disagree. The Examiner has failed to supply a reference or reasoned statement

for generating a subset of the plurality of inputs such that the subset includes data gathered when the receiver was not subject to interference from the therapeutic radiation source. Applicants submit that the only motivation for generating a subset of the inputs is found in the claimed invention. Additionally, the Examiner fails to supply reference or provide a statement that one of ordinary skill would know to include data gathered when the therapeutic radiation source was not interfering with the receiver. In fact, Mate is silent with respect to the therapeutic radiation source signal. Again, Mate is dramatically insufficient in supporting the Examiner's argument, because Mate only states that the "marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways" in order to allow the receiver to differentiate between the marker signal and the excitation source. (Mate, ¶0053) Thus, the Examiner has not satisfied the obviousness standard and for this additional reason the Board should reverse the Examiner's rejection of claim 6.

7. Claims 7, 9 and 10

Claims 7, 9 and 10 depend from base claim 6. Accordingly, Mate cannot support a § 103(a) rejection of dependent claims 7, 9 and 10 for at least the reason that these references cannot support a § 103(a) rejection of base claim 6, and for the additional features of these dependent claims, namely, Mate does not teach or disclose the receiver claimed in claim 6 for use in the treatment of a human; does not teach or disclose a signal line between the therapeutic radiation source and the receiver which carries a signal indicative of activity of the therapeutic radiation source; and does not teach or disclose the receiver claimed in claim 6 wherein the radiation source is a linear accelerator.. Therefore the Board should reverse the Examiner's rejection of claims 7, 9 and 10.

8. Claim 11

Independent claim 11 is directed a method of irradiating a patient with radiation from a therapeutic radiation source, the radiation targeted by the use of a marker associated into the patient. The method includes, *inter alia*, applying an excitation to the marker using an excitation source. The method further includes using a receiver to receive a plurality of

inputs indicative of a sensed magnetic flux induced by said marker in response to the excitation. The method also includes discarding corrupted inputs subject to interference from the therapeutic radiation source from the plurality of inputs to create a subset of the plurality of inputs. The method further includes using a processor to perform an analysis on the subset to locate the marker.

a. The Examiner has not established a *prima facie* case of obviousness of claim 11

Again, to establish a *prima facie* case of obviousness, the Examiner must identify references that teach or suggest all the features of the claim. As discussed with respect to claims 1 and 6 above, Mate does not teach or suggest (**a**) discarding corrupted inputs subject to (**b**) inference from the therapeutic radiation source from the plurality of inputs to (**c**) create a subset of the plurality of inputs. Because this reference is deficient in this regard, the Examiner has not established a *prima facie* case of obviousness of claim 11. For at least this reason the Board should reverse the Examiner's rejection of claim 11.

b. The method of claim 11 is nonobvious to a person of ordinary skill in the pertinent art under the statutory language of § 103(a), as analyzed according to the framework set forth by the Supreme Court

As noted in the previous paragraph, one difference between the subject matter of claim 11 and Mate is that claim 11 recites a feature that includes (**a**) discarding corrupted inputs subject to (**b**) inference from the therapeutic radiation source from the plurality of inputs to (**c**) create a subset of the plurality of inputs. This feature is neither taught nor suggested by the applied reference. Mate discloses methods of separating signal generated by the excitation source from signals generated by the marker source.

These differences are not such that the subject matter of claim 11 as a whole would have been obvious to a person of ordinary skill in the pertinent art. As previously stated, the identified features of claim 11 with elements **a, b and c** are the only teaching provided to the Examiner. Specifically, the Examiner has failed to supply a reference or reasoned statement for creating a subset of the plurality of inputs such that the subset does not

include corrupted inputs, wherein corrupted inputs are subject to interference from the therapeutic radiation source. Additionally, the Examiner fails to supply reference or provide a statement that one of ordinary skill would know to include inputs gathered when the therapeutic radiation source was not interfering with the receiver and discard inputs when the therapeutic radiation source was interfering. As previously noted, Mate is silent with respect to the therapeutic radiation source signal. Applicants submit that the only motivation for generating a subset by discarding corrupt data is found in the claimed invention, and thus, the Examiner has not satisfied the obviousness standard. For this additional reason the Board should reverse the Examiner's rejection of claim 11.

9. Claims 12, 14 and 15

Claims 12, 14 and 15 depend from base claim 11. Accordingly, Mate cannot support a § 103(a) rejection of dependent claims 12, 14 and 15 for at least the reason that these references cannot support a § 103(a) rejection of base claim 11, and for the additional features of these dependent claims, namely, Mate does not teach or disclose the receiver claimed in claim 11 for use in the treatment of a human; does not teach or disclose a signal line between the therapeutic radiation source and the receiver which carries a signal indicative of activity of the therapeutic radiation source; and does not teach or disclose the receiver claimed in claim 11 wherein the radiation source is a linear accelerator.. Therefore the Board should reverse the Examiner's rejection of claims 12, 14 and 15.

10. Claims 3, 8 and 13 are patentable over Mate in view of Acker

Claims 3, 8 and 13 are patentable over Mate in view of Acker for a number of reasons. One reason the Section 103 rejection of these claims is not proper because the cited references fail to teach or suggest all of the claimed features. [MPEP § 706.02(j).] For the reasons explained above, Mate fails to teach or suggest generating a subset of the plurality of inputs. The Examiner does not cite Acker to correct the deficiencies of Mate. Applicants agree that Acker does not correct the deficiencies of Mate. Rather, the

Examiner cites Acker to teach the matched filter for detecting interference, this does not teach or suggest generating a subset of the plurality of inputs. Therefore, the Examiner has not established a *prima facie* case of obviousness with regard to claims 3, 8 and 13.

A second reason is that modifying the Acker invention with the filter of the claimed invention will render the Acker invention inoperable for its intended purpose. Specifically, Acker discloses and teaches an analog or digital band pass filter that is not equivalent to a matched filter. For example, the analog or digital band pass filter disclosed in Acker is an in-line filter designed to reject interference. The claimed matched filter is a separate off-line filter to detect interference. A third reason is that under the statutory language of § 103(a), as analyzed according to the framework set forth by the Supreme Court, claims 3, 8 and 13 are nonobvious to a person of ordinary skill in the pertinent art.

Acker fails to cure the deficiencies of Mate in order to support a Section 103 rejection of claims 3, 8 and 13. Furthermore, since claims 3, 8 and 13 depend from otherwise allowable independent claims 1, 6 and 11, the Section 103 rejections of these dependent claims are improper for the reasons discussed above and for the additional features of these claims. Accordingly, the Board should reverse the Examiner's rejection of these claims.

C. Conclusion

Each of pending claims 1-15 has been improperly rejected for numerous reasons. One reason is that the applied references do not teach or suggest all of the features of each of claims 1-15. Therefore, the Examiner has failed to make a *prima facie* case of obviousness of each claim, and the Examiner thus cannot reject the claims under § 103(a). Each pending claim has been improperly rejected for at least the additional reason that each pending claim is nonobvious to a person of ordinary skill in the pertinent art under the statutory language of 35 U.S.C. § 103(a), as analyzed according to the framework set forth by the Supreme Court. Accordingly, the Board should reverse the Examiner's rejections of pending claims 1-15.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the Examiner is being submitted.

X. RELATED PROCEEDINGS

No related proceedings are referenced in Section II. above, hence copies of decisions in related proceedings are not provided.

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Respectfully submitted,

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VIII. CLAIMS APPENDIX – Appendix A

Claims Involved in the Appeal of Application Serial No. 10/750,164

1. A receiver that receives a plurality of inputs indicative of a sensed magnetic flux induced by a marker, said marker excited by an excitation source, said receiver comprising:

a sensor configured to receive a plurality of inputs;

a correlation processor for analyzing said plurality of inputs in a coherent manner and for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs, wherein inputs that are acquired when a therapeutic radiation source is active are considered corrupted.

2. The receiver of Claim 1 wherein said therapeutic radiation source is used in the treatment of a human.

3. The receiver of Claim 1 further including a matched filter that is adapted to detect interference from said therapeutic radiation source.

4. The receiver of Claim 1 further including a signal line between said therapeutic radiation source and said receiver that carries a signal indicative of activity of said therapeutic radiation source.

5. The receiver of Claim 1 wherein said therapeutic radiation source is a linear accelerator.

6. A method of irradiating a patient with radiation from a therapeutic radiation source, said radiation targeted by the use of a marker associated into said patient, the method comprising:

applying an excitation to said marker using an excitation source;

using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to said excitation;

discarding selected data from said plurality of inputs to generate a subset of the plurality of inputs such that said subset of the plurality of inputs includes data gathered when said receiver was not subject to interference from said therapeutic radiation source; and

using a processor to perform an analysis on said subset of the plurality of inputs in a coherent manner to locate said marker.

7. The method of Claim 6 wherein said therapeutic radiation source is used in the treatment of a human.

8. The method of Claim 6 wherein said receiver includes a matched filter that is adapted to detect interference from said therapeutic radiation source.

9. The method of Claim 6 wherein said receiver includes a signal line between said therapeutic radiation source and said receiver that carries a signal indicative of activity of said therapeutic radiation source.

10. The method of Claim 6 wherein said therapeutic radiation source is a linear accelerator.

11. A method of irradiating a patient with radiation from a therapeutic radiation source, said radiation targeted by the use of a marker associated into said patient, the method comprising:

applying an excitation to said marker using an excitation source;

using a receiver to receive a plurality of inputs indicative of a sensed magnetic flux induced by said marker in response to said excitation;

discarding corrupted inputs subject to interference from said therapeutic radiation source from said plurality of inputs to create a subset of said plurality of inputs; and

using a processor to perform an analysis on said subset to locate said marker.

12. The method of Claim 11 wherein said therapeutic radiation source is used in the treatment of a human.

13. The method of Claim 11 wherein said receiver includes a matched filter that is adapted to detect interference from said therapeutic radiation source.

14. The method of Claim 11 wherein said receiver includes a signal line between said therapeutic radiation source and said receiver that carries a signal indicative of activity of said therapeutic radiation source.

15. The method of Claim 11 wherein said therapeutic radiation source is a linear accelerator.